

## **WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET**

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.\**

*The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

---

\* [https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification\\_Feb2017\\_newtempl.pdf](https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf)

## Information for the patient

[TB333 trade name]<sup>†</sup>  
Ethionamide

*The warnings and instructions in this leaflet are intended for the person taking the medicine.  
If you are a parent or carer responsible for giving the medicine to someone else such as a child,  
you will need to apply the instructions accordingly.*

### **Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours..
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What [TB333 trade name] is and what it is used for
2. What you need to know before you take [TB333 trade name]
3. How to take [TB333 trade name]
4. Possible side effects
5. How to store [TB333 trade name]
6. Contents of the pack and other information

#### **1. What [TB333 trade name] is and what it is used for**

[TB333 trade name] is a medicine used to treat tuberculosis (TB), an infection caused by bacteria called *Mycobacterium tuberculosis*. It is always given together with other medicines to treat tuberculosis. Your healthcare provider has chosen the combination that is right for your condition.

[TB333 trade name] contains the active substance ethionamide. It stops the bacteria multiplying and can kill them by preventing the bacteria from building their cell wall.

#### **2. What you need to know before you take [TB333 trade name]**

##### **Do not take [TB333 trade name]:**

- if you are hypersensitive (allergic) to ethionamide, to protionamide or any of the other ingredients of [TB333 trade name] (see section 6, “What [TB333 trade name] contains”).
- if you have severe liver disease.

##### **Warnings and precautions:**

Always take [TB333 trade name] together with other tuberculosis medicines that your health care provider has asked you to take.

Speak with your health care provider straightaway if you:

- lose your appetite
- get nausea (feel sick)
- have yellowing of your skin or the white parts of your eyes

---

<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory agency’s responsibility.

- pass dark urine
- pass stools that are clay-coloured (or are red or black)
- have belly pain, usually on the right side and near the chest

These are signs of a problem with your liver, which can become serious.

Speak with your health care provider straightaway if you get problems with your eyes (such as eye pain, blurred vision, colour blindness or trouble seeing), numbness, tingling or pain in your hands or feet, unusual bruising or bleeding, swollen breasts (in men), mental changes such as depression, confusion or feeling angry or irritable.

If you get a rash or fever (possible signs of an allergic reaction), tell your health care provider immediately.

Your health care provider will regularly check your blood sugar, blood tests for your thyroid function and your vision during treatment with [TB333 trade name].

Your health care provider may ask you to take pyridoxine (vitamin B6) during treatment with [TB333 trade name]. This vitamin can prevent nerve damage, which is a side effect of [TB333 trade name]. Suggested dose of pyridoxine for adults is 100 mg daily and the dose for children is usually between 10 and 50 mg daily, depending on their weight.

Tell your health care provider about all your symptoms even if you think they are not caused by the tuberculosis infection or your treatment.

#### **Other medicines and [TB333 trade name]**

Tell your health care provider if you are taking or have recently taken any medicines, including medicines obtained without prescription. Some medicines can change how well [TB333 trade name] works, or [TB333 trade name] may change the effect of other medicines you take.

[TB333 trade name] may make the side effects of isoniazid and rifampicin worse.

Do not drink large amounts of alcohol during your treatment with [TB333 trade name].

#### **[TB333 trade name] with food and drink**

You can take [TB333 trade name] with food or between meals. However, taking it with food may reduce side effects on your gut.

#### **Pregnancy and breast-feeding**

You should not become pregnant while on treatment with [TB333 trade name]. If you become pregnant, or are planning to become pregnant, you must contact your health care provider to discuss the effect on your treatment for tuberculosis and on your baby.

It is not known if ethionamide passes into your milk if you are breast feeding. Your baby should have regular checks for ethionamide side effects if you need to breast-feed during [TB333 trade name] treatment.

#### **Driving and using machines**

Ethionamide may cause side effects, such as drowsiness and headache, that can interfere with driving and using machines.

#### **Other ingredient of [TB333 trade name]**

[TB333 trade name] contains 4 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

### **3. How to take [TB333 trade name]**

Always take [TB333 trade name] exactly as your health care provider told you. You should check with your health care provider if you are not sure.

Your health care provider has worked out the right dose of [TB333 trade name] for you. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your health care provider tells you to do so.

### **Adults**

For adults, the usual daily dose is 4 to 8 tablets (500 mg to 1 g daily), depending on your weight and any side effects you get. You can take the dose once a day. However, if you get certain side effects, check with your health care provider if you can split the dose into two doses over the day. Your health care provider may ask you to take 2 tablets on the first day and then gradually increase the dose over a few days, until you reach the dose that is right for you.

#### *Instructions for mixing the tablets for adults*

Mix the right number of [TB333 trade name] in about 50 mL (10 teaspoonfuls) of water in a cup or glass and swallow all the mixture. Use the mixture within 10 minutes. Rinse the cup or glass with a little more water and then swallow it to make sure you take the full dose.

### **Children**

The health care provider will work out the right dose for your child. The daily dose depends on the child's weight and is usually 15 to 20 mg per kg of the child's weight. The child can be given the dose once a day. However, if your child gets certain side effects, check with the health care provider about splitting the dose into two doses over the day. The following doses are recommended for children:

<b>Child's weight</b>	<b>Dose</b>	<b>Amount of water to mix tablets, see Instructions for mixing the tablets, below</b>
3-4.9 kg	See Instructions for mixing the tablets for children weighing less than 7 kg, below	
5-6.9 kg		
7-9.9 kg	1 tablet daily	10 mL (2 teaspoonfuls)*
10-15.9 kg	2 tablets daily	20 mL (4 teaspoonfuls)
16-23.9 kg	3 tablets daily	20 mL (4 teaspoonfuls)
24-45.9 kg	4 tablets daily	40 mL (8 teaspoonfuls)
Over 46 kg	As for adults	

\* If the health care provider feels it is better to use less than 10 mL or if the child needs to split the daily dose into two doses, then the health care provider will explain how to make up the mixture and how much of it to give to the child. You may be given an oral syringe to measure out the mixture if you need to give less than 10 mL

#### *Instructions for mixing the tablets for children weighing 7 kg or more*

You will need a clean cup or glass.

1. Add the required amount of drinking water (5 mL is about 1 teaspoonful) to the cup or glass.
2. Place the required number of [TB333 trade name] into the cup or glass containing the water.
3. Let the tablet or tablets mix in the water, then stir the mixture thoroughly.
4. Give the mixture to your child straightaway and have the child drink all of it.
5. Rinse the empty cup or glass with about 2 teaspoonfuls of drinking water and have the child drink it to make sure that your child has taken all the dose.

#### *Instructions for mixing the tablets for children weighing less than 7 kg*

You will need a clean cup or glass. You will also be given an oral syringe to measure out the mixture you give to your child.

1. Add 10 mL of drinking water to the cup or glass.
2. Place 1 tablet into the cup or glass containing the water.
3. Let the tablet mix in the water, then stir the mixture thoroughly.
4. The amount of mixture to give to your child depends on the child's weight:

<b>Child's weight</b>	<b>Amount of mixture to give</b>
3–4.9 kg	3 mL daily
5–6.9 kg	7 mL daily

5. Using an oral syringe, measure out the right amount of mixture for your child and have the child drink all of it straightaway.

#### ***Liver disease***

If you have severe liver disease, you must not take [TB333 trade name] (see “Do not take [TB333 trade name]”).

#### **If you take more [TB333 trade name] than you should**

If you have taken too many tablets or if someone accidentally swallows some, there is no immediate danger. However, you should contact your health care provider or the nearest hospital emergency department for advice.

#### **If you forget to take [TB333 trade name]**

If you miss a dose and notice within 6 hours, take the missed dose as soon as possible. Take the next regular dose as scheduled. If more than 6 hours have passed since you should have taken the dose, then simply wait to take your next dose when it is due. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking [TB333 trade name]**

Keep taking the medicine for as long as your health care provider has told you, even if you are feeling better. If you stop the medicine too soon, your infection may not be cured and it may become more difficult to treat it.

You should not stop treatment unless your health care provider tells you to.

If you have any further questions on the use of this medicine, ask your health care provider.

#### **4. Possible side effects**

Like all medicines, [TB333 trade name] can cause side effects, although not everybody gets them. It is not always possible to say which unwanted effects are caused by [TB333 trade name] and which are caused by any other medicines you may also be taking.

For this reason, it is important that you tell your health care provider of any change in your health.

The *most common* side effects (which can occur in more than 1 person in 10 who take the medicine) are stomach discomfort, abdominal (belly) pain, loss of appetite, vomiting, diarrhoea, and nausea (feeling sick). How often these side effects occur depends on the dose and duration of therapy.

Blood tests that show stress on the liver (increased liver enzymes called serum transaminases) can also occur very commonly in people taking [TB333 trade name].

Other *common* side effects (which can occur in more than 1 person in every 100 who take the medicine) are headache, dizziness, drowsiness, general weakness, feeling of pins and needles (paraesthesia), inflammation of the liver (hepatitis) and yellowing of the skin.

The following side effects can occur in people treated with ethionamide. However, it is not known how often they occur:

- decrease of platelets (blood cells important for blood clotting);
- metallic taste and sulphurous belching;
- increased salivation;
- taste changes;

- so-called Pellagra-like syndrome (with diarrhoea, skin inflammation and problems with brain function, caused by a lack of niacin, a type of vitamin);
- reduced thyroid function;
- raised sugar in the blood;
- psychotic reactions (hallucinations, abnormal thinking, personality changes);
- low blood pressure (especially after standing up);
- altered brain function and brain disorder (encephalopathy);
- tingling in the arms and legs;
- altered sense of smell;
- rash (red, raised or itchy), red or purple discolouration on the skin (purpura), itchy rash (urticaria), acne;
- sensitivity to light (photosensitivity);
- inflammation of mucous lining (cheeks, gums, tongue, lips, throat);
- hair loss;
- breast enlargement in men;
- menstrual disturbance;
- impotence;
- visual disturbance (blurred or double vision, complete or partial loss of vision);
- damage to the ear (e.g. dizziness, hearing loss, tinnitus);
- fever.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your health care provider as soon as possible.

### **Reporting of side effects**

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

## **5. How to store [TB333 trade name]**

Keep this medicine out of the sight and reach of children.

Store below 30°C in dry place. Protect from light.

Do not use this medicine after the expiry date stated on the label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What [TB333 trade name] contains**

- The active ingredient is 125 mg ethionamide.
- The other ingredients of [TB333 trade name] are aspartame, colloidal anhydrous silica, corn starch, crospovidone, low substituted hydroxypropyl cellulose, magnesium stearate, menthol, microcrystalline cellulose, peppermint flavour, povidone, sodium chloride and sucralose.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

### **What [TB333 trade name] looks like and contents of the pack**

Yellow coloured, circular, biconvex, uncoated tablets having angular break line on one side and plain surface on the other side.

The tablet can be divided into equal doses.

#### *Alu/Alu strip packs:*

Pack sizes: Strips of 6 tablets. Such 5 strips are kept packed in a carton (6 x 5 tablets)

Pack sizes: Strips of 10 tablets. Such 10 strips are kept packed in a carton (10 x 10 tablets)

### **Supplier and Manufacturer**

#### ***Supplier***

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade  
Marol Church road  
Andheri (East)  
Mumbai – 400 059  
India  
Tel: +91-22-66762800  
Fax: +91 -22-28216599  
E-mail: [exports@macleodspharma.com](mailto:exports@macleodspharma.com)  
[vijay@macleodspharma.com](mailto:vijay@macleodspharma.com)  
[sjadhav@macleodspharma.com](mailto:sjadhav@macleodspharma.com)

#### ***Manufacturer***

Macleods Pharmaceuticals Limited  
Phase II, Unit II  
Plot No 25-27, Survey No 366  
Premier Industrial Estate  
Kachigam, Daman, 392 210  
India  
Tel: +91 260 2241565, +91 22 28216599  
Fax: + 91 260 2241565  
E-mail: [nishata@macleodspharma.com](mailto:nishata@macleodspharma.com)

For any information about this medicine, contact the local representative of the supplier.

**This leaflet was last revised in May 2023.**

*Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/pqweb/medicines>*